



DT04 Rec'd PCT/PTO 26 JAN 2004 PCT
Attorney's Docket No.: 07763-042001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Gennaro et al. Art Unit : Unknown
Serial No. : 10/009,384 Examiner : Unknown
Filed : November 2, 2001
Title : SECRETED PROTEINS OF MYCOBACTERIUM TUBERCULOSIS AND
THEIR USE AS VACCINES AND DIAGNOSTIC REAGENTS

Box: PCT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO DECISION ON PETITION UNDER 37 CFR 1.47(a)

In response to the Decision on Petition under 37 CFR 1.47(a) mailed December 18, 2003, Applicants submit herewith a Declaration and Power of Attorney signed by inventor Manuel J. Gomez. In light of this submission, Applicants respectfully request that examination of the instant application be allowed to proceed.

In addition, in footnote 1 on page 1 of the Decision on Petition under 37 CFR 1.47(a), it is stated that, because an International Preliminary Examination Report (IPER) had not issued at the time the instant national stage application was filed, Applicants are required to pay a small entity basic national filing fee of \$355 rather than the \$50 fee actually paid by Applicants. The footnote also states that Deposit Account 06-0150 would be charged \$305 to bring the fee payment to the required amount. Applicants respectfully request that the \$305 amount be refunded for the following reasons. First, Applicants submit that it is unfair that they be penalized when, through no fault of their own, an IPER had not been mailed at the deadline for

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

JANUARY 23, 2004

Date of Deposit

Signature

Maryann White
MARYANN WHITE

Typed or Printed Name of Person Signing Certificate

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filing of the instant national stage application. In addition, an IPER, a copy of which is enclosed, issued subsequent to the filing of the instant application.

Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,



Date: 1/23/04

Stuart Macphail, Ph.D.
Reg. No. 44,217

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PATENT COOPERATION TREATY

07763/042WO1/WH
RECEIVED
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 FISH & RICHARDSON, P.C.
 NEW YORK CITY OFFICE

From the
 INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
 WILLIAM J. HONE
 FISH & RICHARDSON P.C.
 45 ROCKEFELLER PLAZA
 SUITE 2800
 NEW YORK, NY 10111

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing (day/month/year)	
Applicant's or agent's file reference	
07763/042WO1	
IMPORTANT NOTIFICATION	
International application No.	International filing date (day/month/year)
PCT/US00/12197	04 May 2000 (04.05.2000)
Applicant	Priority date (day/month/year)
	04 May 1999 (04.05.1999)
THE PUBLIC HEALTH RESEARCH INSTITUTE OF THE CITY OF NEW YORK	

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

* No Docketing Required *

Reviewed By Practice Systems
 Initials:

Reviewed By Billing Secretary
 Initials:

and mailing address of the IPEA/US
 Commissioner of Patents and Trademarks
 Box PCT
 Washington, D.C. 20231
 No. (703)305-3230
 PEA/416 (July 1992)

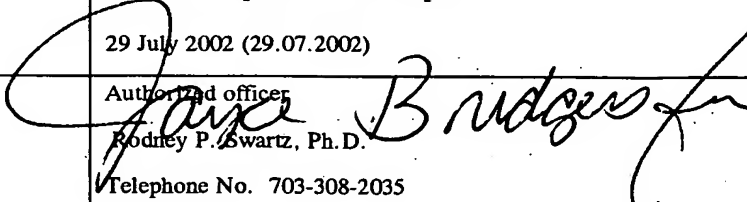
Authorized officer
Rodney P. Swartz, Ph.D.
 Telephone No. 703-308-2035

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 07763/042WO1	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/12197	International filing date (day/month/year) 04 May 2000 (04.05.2000)	Priority date (day/month/year) 04 May 1999 (04.05.1999)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 38/00, 39/00, 39/02, 39/04; C07H 21/02, 21/04; C07K 1/00, 14/00; C12N 1/12, 1/20; C12P 19/34, 2 and US Cl.: 424/185.1, 234.1, 248.1; 435/69.1, 71.1, 91.1, 253.1; 530/300, 350; 536/22.1, 23.1, 23.7		
Applicant THE PUBLIC HEALTH RESEARCH INSTITUTE OF THE CITY OF NEW YORK		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none">I <input checked="" type="checkbox"/> Basis of the reportII <input type="checkbox"/> PriorityIII <input checked="" type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicabilityIV <input type="checkbox"/> Lack of unity of inventionV <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statementVI <input type="checkbox"/> Certain documents citedVII <input type="checkbox"/> Certain defects in the international applicationVIII <input checked="" type="checkbox"/> Certain observations on the international application		
Date of submission of the demand 04 December 2000 (04.12.2000)	Date of completion of this report 29 July 2002 (29.07.2002)	
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer  Rodney P. Swartz, Ph.D. Telephone No. 703-308-2035	

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/12197

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-22 _____ as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____
- ☒ the claims:
pages 23-30 _____, as originally filed
pages NONE _____, as amended (together with any statement) under Article 19
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____
- ☒ the drawings:
pages 1-26 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages NONE _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 21-36

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 21-36

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.

- ☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/12197

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement.

1. STATEMENT

Novelty (N)	Claims <u>1-20</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-20</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-20</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-20 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the specific MTSP polypeptides or DNA encoding the specific MTSP polypeptides. The previously cited references teach what appear to be other specific polypeptides commensurate with the description and scope of the instant MTSP polypeptides. However, because the application does not contain a computer readable file of the sequences, a comprehensive determination of the MTSP polypeptides in the prior art was restricted to the words "MTSP" and the physical description of the polypeptides.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

The drawings are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 7 because: the brief description of Figure 4 on page 10 recites that "Fig. 4 is an enlargement of Fig. 3C". However, Fig. 3C and Fig 4 are identical in size and content.

Claims 1-20 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because of the claims are not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art because: the description teaches only the computer aided prediction of polypeptides which might be obtained from the already known DNA of *M. tuberculosis* and the description indicates that some of the regions of DNA coding regions are specific for the *M. tuberculosis* complex. However, the description does not actually contain examples of: 1) polypeptides that have "*M. tuberculosis* specific antigenic and immunogenic properties", 2) vectors containing the claimed DNA, 3) cells transformed by such vectors, 4) DNA vaccines, 5) methods of diagnosis using polypeptides.

Claims 1-20 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because of the claims are not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art because: the description teaches only the computer aided prediction of polypeptides which might be obtained from the already known DNA of *M. tuberculosis* and the description indicates that some of the regions of DNA coding regions are specific for the *M. tuberculosis* complex. However, the description does not teach diagnosis in a subject "being susceptible to *M. tuberculosis* infection" nor how one detects an immune response in said subject not previously exposed to *M. tuberculosis* nor how one detects whether a subject is "susceptible" to *M. tuberculosis* infection by mere administration of a polypeptide composition.